

MAY 21 1996

K960705

Section 2 - Summary of Safety and Effectiveness and Class III Certification and Summary

a. Summary Of Safety And Effectiveness

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Device Name

Guglielmi Detachable Coil (GDC), Class III.

Device Description

The GDC system consists of a remote power supply and an occlusion coil attached to a delivery wire. The occlusion coil is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy. The occlusion coils are manufactured from a platinum wire which is wound into a primary coil, and formed into a secondary helical or curved shape. The delivery wire consists of a stainless steel core wire with a stainless steel coil soldered on at the distal end and a Teflon outer jacket proximal to the detachment zone.

Intended Use

The Guglielmi Detachable Coil (GDC) is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be: a) very high risk for management by traditional operative techniques, or, b) inoperable, and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature.

Predicate Devices

Target Therapeutics intends to expand the indications for the Guglielmi Detachable Coils (GDC) to include other vascular lesions such as arteriovenous malformations (AVM) and arteriovenous fistulas (AVF). The GDC is substantially equivalent to coils currently marketed by Target Therapeutics and the Cook company for use in vascular lesions such as arteriovenous malformations and arteriovenous fistulae of the peripheral and neuro vasculature.

Indications for Use Comparison Chart

GDC with expanded indications	for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be a)very high risk for management by traditional operative techniques, or b) inoperable and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neuro vasculature.
GDC (K951256)	for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be a)very high risk for management by traditional operative techniques, or b) inoperable
COOK OCCLUSION COILS	for embolization of selective vessel supply to arteriovenous malformations and other vascular lesions of the brain, spinal cord, spine and other small vessel applications.
ARTIFICIAL EMBOLIZATION DEVICE (CFR 21 Section 882.5950)	<i>Identification:</i> An artificial embolization device is an object that is placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation